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CPA/1635

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

CONTINUED PROSECUTION APPLICATION (CPA)
REQUEST TRANSMITTAL

(only for Continuation or Divisional applications under 37 CFR 1.53(d))

TECH CENTER 1600/290

Docket No.: 19603/607 (CRF D-1657C)
Express Mail No.: EL709323585US
Examiner: J. Zara
Art Unit: 1635

Assistant Commissioner for Patents
Washington, D.C. 20231
BOX: CPA

#15 / R.T.
9/25
CPA

This is a Request for filing a:

- ☒ continuation or
☐ divisional application

under 37 CFR 1.53(d), continued prosecution application, (CPA) of prior application number 09/428,371, filed on October 28, 1999, of Soderlund et al. entitled INSECT SODIUM CHANNELS FROM INSECTICIDE-SUSCEPTIBLE AND INSECTICIDE-RESISTANT HOUSE FLIES.

The above-identified prior pending application is hereby expressly abandoned as of the filing date of this request for a continued prosecution application (CPA).

1. ☐ Enter the unentered amendment previously filed on [*enter date] under 37 CFR 1.116 in the prior nonprovisional application.
2. ☒ A Request for Reconsideration (4 pages) with Exhibits 1-3 is enclosed.
3. ☐ This application is filed by fewer than all the inventors named in the prior application, 37 CFR 1.53 (d)(4).
 - a. ☐ Delete the following inventor(s) named in the prior nonprovisional application:

 - b. ☐ The inventor(s) to be deleted are set forth on a separate sheet enclosed herewith.
4. ☐ A new power of attorney is enclosed herewith.
5. ☐ Information Disclosure Statement (IDS) with PTO-1449 form(s) and a copy of 1 reference is enclosed herewith.
6. The filing fee is calculated on the basis of the claims existing in the prior application as amended above:

09/14/2001 CNGUYEN 00000025 09428371

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	(Col. 1)	(Col. 2)	SMALL ENTITY			LARGE ENTITY	
FOR:	NO. FILED	NO. EXTRA	RATE	FEE	OR	RATE	FEE
BASIC FEE	XXXXXXXXXX	XXXXXXXXXX	XXXXXX	\$355	OR	XXXXXX	\$710
TOTAL CLAIMS	18 - 20 =	0	x 9 =	\$	OR	x 18 =	\$0
INDEP CLAIMS	1 - 3 =	0	x 40 =	\$	OR	x 80 =	\$0
[] MULTIPLE DEPENDENT CLAIM PRESENTED			x135 =	\$	OR	x270 =	\$0
*If the Total Claims are less than 20 and Indep. Claims are less than 3, enter "0" in Col. 2			TOTAL	\$355	OR	TOTAL	\$


7. [X] A check in the amount of **\$355.00** is enclosed to cover the above filing fee.
8. [X] The Commissioner is hereby authorized to charge fees which may be required, or credit overpayment to Deposit Account No. 14-1138. A duplicate copy of this sheet is enclosed.
9. Small entity status:
- [X] Applicant claims small entity status. (See 37 CFR 1.27.)
- [] A small entity statement was filed in the prior nonprovisional application and such status is still proper and desired.
- [] is no longer claimed.
10. [X] Request for Five-Month Extension of Time in prior application.
11. [X] A self-addressed, prepaid postcard for acknowledging receipt.
12. Other:

Address all future communications to (may only be completed by Applicant, or attorney or agent of record):

Michael L. Goldman, Esq.
NIXON PEABODY LLP
Clinton Square
P.O. Box 31051
Rochester, New York 14603-1051

Respectfully submitted,

Date: September 10, 2001


Michael L. Goldman
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EXPRESS MAIL CERTIFICATE

DOCKET NO. : 19603/607 (CRF D-1657C)
APPLICANTS : David M. Soderlund, Douglas C. Knipple, and Patricia J. Ingles
TITLE : INSECT SODIUM CHANNELS FROM INSECTICIDE-
SUSCEPTIBLE AND INSECTICIDE-RESISTANT HOUSE
FLIES

Certificate is attached to the **Continued Prosecution Application (CPA)**
Request Transmittal Letter (2 pages) of the above-named application.

"EXPRESS MAIL" NUMBER: **EL709323585US**
DATE OF DEPOSIT: **September 10, 2001**

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231 **Box: CPA.**

Ruth R. Smith
(Typed or printed name of person mailing
paper or fee)

Ruth R. Smith
(Signature of person mailing paper or fee)



PATENT
Docket No.: 19603/607 (CRF D-1657C)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : David M. Soderlund, Douglas C. Knipple, and
Patricia J. Ingles
Serial No. : CPA of 09/428,371
Cnfrm. No. : 4568
Filed : Herewith
For : INSECT SODIUM CHANNELS FROM
INSECTICIDE-SUSCEPTIBLE AND
INSECTICIDE-RESISTANT HOUSE FLIES

Examiner:
J. Zara
Art Unit:
1635

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RECONSIDERATION

REQUEST FOR RECONSIDERATION

Assistant Commissioner for Patents
Washington, D.C. 20231
Box: CPA

Dear Sir:

In response to the August 10, 2000, final rejection and the March 31, 2001, advisory action, applicants respectfully request reconsideration.

The rejection of claims 41-52 and 78-83 under 35 U.S.C. § 112 (first paragraph) for lack of enablement is respectfully traversed.

The arguments made in applicants' June 5, 2000, and February 9, 2001, amendments are hereby reiterated. In maintaining this rejection, the advisory action notes that applicants have not demonstrated that the nucleotide sequences of SEQ. ID. Nos. 1 and 2 encode functional voltage sensitive sodium channels. Applicants respectfully disagree.

SEQ. ID. No. 1 is the nucleotide sequence of the *Vssc1* gene of the wild-type house fly. The wild-type *Vssc1* gene is referred to in the art as either *Vssc1*^{NAIDM} or *Vssc1*^{wt} and was deposited by applicants as ATCC Accession No. U38813 (Ingles et al., "Characterization of Voltage-Sensitive Sodium Channel Gene Coding Sequences from Insecticide-Susceptible and Knockdown-Resistant House Fly Strains (Rapid Communication)" Insect Biochem. Mol. Biol. 26(4):319-326, at 321 (1996) ("Ingles I")

(enclosed with applicants' Information Disclosure Statement, dated October 28, 1999) and Ingles et al., "Characterization of Voltage-Sensitive Sodium Channel Gene Coding Sequences from Insecticide-Susceptible and Knockdown-Resistant House Fly Strains (Corrigendum)," Insect Biochem. Mol. Biol. 27(1):V (1997) ("Ingles II") (attached hereto as Exhibit 1)). The copy of the GenBank listing for Accession No. U38813 (attached hereto as Exhibit 2) demonstrates that it has the same nucleotide sequence as that of SEQ. ID. No. 1 of the present application. SEQ. ID. No. 2 is the nucleotide sequence of the *Vssc1* gene of the 538ge strain of house fly, which strain is known to be insecticide-resistant (Ingles I, pp. 319-20). The 538ge *Vssc1* gene is referred to in the art as *Vssc1*^{538ge}, and was deposited by applicants as ATCC accession number U38814 (Ingles I, p. 324). The copy of the GenBank listing for Accession No. U38814 (attached hereto as Exhibit 3) demonstrates that it has the same nucleotide sequence as that of SEQ. ID. No. 2 of the present application. As demonstrated below, there is more than sufficient evidence to show that the nucleic acids of SEQ. ID. Nos. 1 and 2 encode proteins that function as a voltage-sensitive sodium channels.

As previously discussed in applicants' Amendment Under 37 CFR § 1.116, dated February 9, 2001 ("Final Amendment"), Smith et al., "The L1014F Point Mutation in the House Fly *Vssc1* Sodium Channel Confers Knockdown Resistance to Pyrethroids," Insect Biochem. Molec. Biol. 27(10):807-12 (1997) ("Smith I") (attached to applicants' Final Amendment as Exhibit 1) contains data demonstrating that various proteins function as sodium channels. With regard to the protein encoded by a nucleic acid having the nucleotide sequence of SEQ. ID. No. 1, it should be noted that amongst the proteins tested as a voltage sensitive sodium channel was that of insecticide-susceptible wildtype (*Vssc1*^w) (See p. 807 of Smith). This protein is said to be encoded by the same nucleic acid as the *Vssc1*^{NAIDM} cDNA described in Ingles I. Thus, the results in Smith for the *Vssc1*^w protein can clearly be correlated to the nucleic acid having the nucleotide sequence of SEQ. ID. No. 1 and the amino acid sequence of SEQ. ID. No. 3 for the present application. Turning again to Smith I, Figure 1(a) shows that *Xenopus* oocytes injected with cRNA encoding wild-type *Vssc1* proteins produce sodium currents in response to an applied voltage (pp. 808-809). Thus, Smith I shows that the protein having the amino acid of SEQ. ID. No. 2, which is encoded by the nucleic acid having the nucleotide sequence at SEQ. ID. No. 1 is a functional voltage-sensitive sodium channel.

As to nucleic acid having the nucleotide sequence of SEQ. ID. No. 2 which encodes a protein having an amino acid sequence of SEQ. ID. No. 4, there is also ample evidence of a functional voltage-sensitive sodium channel protein. Applicants have

established a very high level of sequence homology between the nucleic acids having the nucleotide sequences of SEQ. ID. Nos. 1 and 2 (see pages 4-5, 13-14, and 34-35 of the present application; Ingles I, pages 319 and 324; Ingles II). As applied to nucleic acid corresponding to SEQ. ID. No. 2 and the protein of SEQ. ID. No. 4, applicants respectfully disagree with the statement in the advisory action that "[h]omology does not imply function." Smith I reports the functional expression of mutant *VsscI* proteins as voltage-sensitive sodium channels (p. 809 and Figure 2 on p. 810). This mutant *VsscI* protein was made by introducing a single point mutation to the wild-type *VsscI* protein by substituting phenylalanine for leucine at position 1014 of the inferred amino acid sequence of the wild-type *VsscI* protein (p. 808). This single substitution made the wild-type *VsscI* protein take on the insecticide-resistant characteristics of the *VsscI*^{538ge} protein (p. 811). Further, the mutant *VsscI* proteins, like the wild-type *VsscI* protein, were expressed in *Xenopus* oocytes and shown to function as voltage-sensitive sodium channels (p. 808-809). Thus, there is more than sufficient evidence to demonstrate that small mutations to the *VsscI* protein do not alter that protein's function as a voltage sensitive sodium channel and one of ordinary skill in the art would expect the protein encoded by the *VsscI*^{538ge} gene, which corresponds to the amino acid and nucleotide sequences of SEQ. ID. Nos. 4 and 2, respectively, to function as voltage sensitive channels. See also Lee et al., "The V410M Mutation Associated with Pyrethroid Resistance in *Heliothis virescens* Reduces the Pyrethroid Sensitivity of House Fly Sodium Channels Expressed in *Xenopus* Oocytes," Insect Biochem. Molec. Biol. 31:19-29 (2000) (attached to the Final Amendment as Exhibit 5).

Since the ability of the subject proteins to function as voltage sensitive sodium channels has been demonstrated, the enablement rejection should be withdrawn.

In view of all the foregoing, it is submitted that this application is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

Date: September 10, 2001



Michael L. Goldman
Registration No. 30,727

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